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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,095	09/18/2003	Robert P. Hammer	Hammer 0212.1	6953

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,095	HAMMER ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-18,20,21 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8,20,21 and 51-53* is/are rejected.

7)☒ Claim(s) *4,9-18 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20051223*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Sequence Listing filed December 23, 2005 is approved.

2. Claims 53 and 54 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/412,081 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

Instant claims 1, 2, 4-18, 20, 21, 51, and 52 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/412,081 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose all of the generic formulas recited in instant claims 1 and 51; does not disclose the additional functionalities of instant claim 1, part (d); does not disclose the size limitations of instant claim 1, part (e); does not disclose compounds corresponding to SEQ ID NOS:5, 6, and 7; does not disclose aggregation-inducing sequences corresponding to SEQ ID NOS:9-16 or Q_m where m is an integer from 25 to 45; and does not disclose combining the compounds with a pharmaceutically acceptable carrier in general. Note that unless a claim is limited exclusively to subject matter disclosed in a priority application, the claim is not entitled to the benefit of the filing date of the priority application. See MPEP 201.11(I) and (VI).

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 7, 8, 20, 51, and 52 are rejected under 35 U.S.C. 102(b) and claim 53 is rejected under 35 U.S.C. 102(a) as being anticipated by the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001). The Fu et al article teaches Applicants' elected peptide, Lys-Digb-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2. See page 239, column 1. This peptide corresponds to, e.g., the fifth peptidyl sequence of claim 1 wherein X_{aa1} is Lys,

Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, n=0, and the C-terminal end comprises an additional functionality (i.e. Dpg-Lys_6-NH_2) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality. This peptide also corresponds to, e.g., the ninth peptidyl sequence of claim 1 wherein n=0, X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, Y_{AA3} is Dpg, and the C-terminal end comprises an additional functionality (i.e. Lys_6-NH_2) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality.

5. Claims 1 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fu et al article (J. Org. Chem., Vol. 66, pages 7118-7124). The Fu et al article teaches the peptide Lys-Dbg-Ala-Dpg-Glu-NH_2. See Figure 3A. The peptide of the Fu et al article corresponds to the first peptidyl sequence of claim 1 wherein X_{aa1} is Lys, Y_{AA1} is Dbg, X_{aa2} is Ala, Y_{AA2} is Dpg, S is Glu, and n=1. The peptide also corresponds to the second peptidyl sequence of claim 1 wherein n=0, X_{aa1} is Lys, Y_{AA1} is Dbg, X_{aa2} is Ala, Y_{AA2} is Dpg, and the C-terminal end comprises an additional functionality (i.e. Glu) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality. The peptide also corresponds to the third peptidyl sequence of claim 1 wherein Y_{AA1} is Dbg, X_{aa1} is Ala, Y_{AA2} is Dpg, X_{aa2} is Glu, n=0, and the N-terminal end comprises an additional functionality (i.e. Lys) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality. The peptide

also corresponds to the fourth peptidyl sequence of claim 1 wherein S is Lys, n=1, Y_{AA1} is Dbg, X_{aa1} is Ala, Y_{AA2} is Dpg, and X_{aa2} is Glu. The peptide also corresponds to the fifth and sixth peptidyl sequences of claim 1 wherein X_{aa1} is Lys, Y_{AA1} is Dbg, X_{aa2} is Ala, Y_{AA2} is Dpg, X_{aa3} is Glu, and n=0. In view of the similarity in structure between the peptide of the Fu et al article and Applicants' claimed peptidyl sequences, the peptide of the Fu et al article inherently will be capable of inhibiting the toxicity of an amyloid protein or amyloid peptide to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present the peptide of the Fu et al article and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the peptide of the Fu et al article. Note that patentability is not imparted to product claims merely upon the employment of descriptive language not chosen by the prior art. In re Skoner, 186 USPQ 80, 82 (CCPA 1975). The discovery of a new property or use for a previously known compound can not impart patentability to claims drawn to the compound. In re Schoenwald, 22 USPQ2d 1671 (CAFC 1992).

6. Claims 1, 2, 6-8, 20, 21, 51, and 52 are rejected under 35 U.S.C. 102(a) as being anticipated by the Fu dissertation (Louisiana State University, December 2002). The Fu dissertation teaches peptides at page 24, Table 2.1, and at page 123, Table 5.1, and at page 126, peptides AMY-3 and AMY-4, which comprise the same peptidyl sequences recited in instant claim 1. For example, DPG-4 of the Fu dissertation corresponds to the eighth peptidyl sequence of claim 1 wherein (S) is Lys and n=1, Y_{AA1} is Dpg, X_{aa1} is Val, Y_{AA2} is Dpg, X_{aa2} is Thr, Y_{AA3} is Dpg, X_{aa3} is Val, and the C-terminal end comprises an additional functionality (i.e. Dpg-Glu) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or

amyloid peptide as compared to an otherwise identical compound lacking such additional functionality. Alternatively, DPG-4 corresponds to the ninth peptidyl sequence of claim 1 wherein n=0, X_{aa1} is Lys, Y_{AA1} is Dpg, X_{aa2} is Val, Y_{AA2} is Dpg, and X_{aa3} is Thr, Y_{AA3} is Dpg, and the C-terminal end comprises an additional functionality (i.e. Val-Dpg-Glu-NH_2) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality. The peptides of Table 2.1 of the Fu dissertation are combined in phosphate-buffered aqueous solution (see page 30), which corresponds to the pharmaceutically acceptable carrier of instant claim 21. In view of the similarity in structure between the peptides of the Fu dissertation and Applicants' claimed peptidyl sequences, the peptides of the dissertation inherently will be capable of inhibiting the toxicity of an amyloid protein or amyloid peptide to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present the peptides of the Fu dissertation and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the peptides of the Fu dissertation. Note that patentability is not imparted to product claims merely upon the employment of descriptive language not chosen by the prior art. In re Skoner, 186 USPQ 80, 82 (CCPA 1975). The discovery of a new property or use for a previously known compound can not impart patentability to claims drawn to the compound. In re Schoenwald, 22 USPQ2d 1671 (CAFC 1992). The Fu dissertation also teaches the peptide AMY-1, which corresponds to Applicants' elected SEQ ID NO:4 and which is combined with a phosphate-buffered aqueous solution, and the peptide AMY-2, which corresponds to Applicants' SEQ ID NO:7. See pages 103, 108, and 126.

7. Claims 1, 2, 5, 7, 8, 20, 21, 51, and 52 are rejected under 35 U.S.C. 102(a) as being anticipated by the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003. The Aucoin oral presentation, as evidenced by the presentation notes supplied in the Information Disclosure Statement filed September 18, 2003, disclosed peptides AMY-1 and AMY-3 which correspond to Applicants' claimed compounds of SEQ ID NOS:4 and 6, respectively. The peptides are combined with a phosphate-buffered aqueous solution, which corresponds to Applicants' pharmaceutically acceptable carrier.

The Aucoin oral presentation satisfies the requirement of 35 U.S.C. 102(a) that an invention be "known... by others in this country" because the identity of the presenter is different than the inventorship of the instant application, and any difference in authorship/inventorship satisfies the statutory requirement of "by another". See MPEP 2132(III). See also Ecolochem Inc. v. Southern California Edison, 56 USPQ2d 1065, 1071 (CAFC 2002), where the court acknowledges that oral presentations can satisfy the requirements of 35 U.S.C. 102(a). This rejection could be overcome, e.g., by the submission of a declaration under 37 CFR 1.132 showing that the subject matter of the presentation was derived from the instant inventors and was therefore not "by another". See MPEP 715.01(c), 716.10, and 2136.05.

Note that the Aucoin oral presentation is not considered to be a printed publication because insufficient evidence is of record as to whether printed copies, slides, etc. of oral presentation were made available and/or whether members of the public had time to make copies of the disclosed subject matter. Compare In re Klopfenstein, 72 USPQ2d 1117 (CAFC 2004).

8. Applicant's arguments filed December 23, 2005 have been fully considered but they are not persuasive.

It should be noted that while one of the generic peptidyl sequences was deleted from claim 1, peptides having the amino acid sequence of Applicants' SEQ ID NO:4 will correspond to others of the generic peptidyl sequences recited in claim 1. See, e.g., the revised rejection over the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001).

With respect to claims 53 and 54, Applicants and the examiner are in agreement that the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001) is available as prior art against these claims only under 35 U.S.C. 102(a). Applicants and the examiner are also agreement that not all of the inventors listed in the declaration need to be inventors of every pending claim. However, the declaration by Hammer under 37 CFR 1.132 filed December 23, 2005 does not explicitly state who the inventors are of the subject matter recited in instant claims 53 and 54. With respect to claim 54, the declaration does state that Inventors McLaughlin, Fu, Miller, and Hammer are the inventors of the peptide AMY-1 (see section 5 of the declaration). Because claim 54 is limited to this single compound, the examiner can make the inference that only Inventors McLaughlin, Fu, Miller, and Hammer are the inventors of the subject matter claimed in claim 54. Accordingly, the Hammer declaration shows that, with respect to the subject matter of claim 54, the Fu et al article is not "by another" and is therefore unavailable as prior art under 35 U.S.C. 102(a). Claim 53 presents a different fact situation. Claim 53 is not limited to the single compound AMY-1, the declaration does not state who is the inventor of the subject matter of claim 53, and the examiner is unable to make any

inference as to who invented the subject matter of claim 53. Accordingly, all six of the inventors listed in the declaration are presumed to be the inventors of the subject matter of claim 53. The peptide AMY-1, disclosed by the Fu et al article and which the declaration states was invented by Inventors McLaughlin, Fu, Miller, and Hammer, is still "by another" and remains available as prior art under 35 U.S.C. 102(a).

The rejection of claims 1 and 52 over the Fu et al article (J. Org. Chem., Vol. 66, pages 7118-7124) is maintained. The similarity between the peptide amino acid sequence taught by the reference and the generic formulas recited in Applicants' claims is sufficient to establish prima facie anticipation. The Office does not have to identify an amyloid aggregation-inducing sequence for which the recited X and Y amino acids are identical or homologous to alternating amino acids of the aggregation-inducing sequence of the amyloid protein or amyloid peptide because other evidence is of record which is sufficient to establish prima facie anticipation, and because, as noted in the rejection, patentability is not imparted to product claims merely upon the employment of descriptive language not chosen by the prior art. In re Skoner, 186 USPQ 80, 82 (CCPA 1975). The examiner agrees that the prima facie case of anticipation could be rebutted by showing, e.g., that the amino acid residues present in the peptide of the Fu et al article are not identical or homologous to alternating amino acids of the aggregation-inducing sequence of an amyloid protein or amyloid peptide (see claim 1, parts (a) and (b)). However, Applicants have not made such a showing. At page 6, sixth full paragraph, of the response, Applicants state that the peptide of the Fu et al article is not an analog of or homologous to any known amyloid-inducing sequence, including the threonyl-tRNA synthetase from Streptomyces avermitilis which was identified by a sequence search of Lys-Phe-Ala-Ala-Glu. However, the claims are not

limited to inhibitors of "known" amyloid proteins or amyloid peptides, but embrace the inhibitors of any amyloid protein or amyloid peptide. Applicants' statement does not rebut the prima facie case of anticipation because it is based upon a limitation not found in the rejected claims. Further, Applicants' statement considers only one analog/homologous sequence, Lys-Phe-Ala-Ala-Glu. The peptide of the Fu et al article is analogous/homologous to more than one sequence (e.g., where Arg or His are present instead of Lys; where Tyr or Trp are present instead of Phe; where Pro, Gly, Ser or Thr are present instead of Ala; and/or where Asp is present instead of Glu). Also, Applicants' sequence search did not take into account the limitation of claim 1, step (e), i.e. that the peptide of the Fu et al article does not have to have the same number of amino acids as the aggregation sequence of the amyloid protein or amyloid peptide. Accordingly, Applicants' search of a single sequence does not prove that the Fu et al article's peptide is not an analog of or homologous to any amyloid protein or amyloid peptide. Finally, the rejection shows that the peptide of the Fu et al article corresponds to several of the generic formulas recited in instant claim 1, and that not all of the amino acid residues present in the peptide of the Fu et al article necessarily correspond to the X or Y residues of Applicants' generic formulas. Applicants' sequence search, on the other hand, assumes that all five of the residues must be identical or homologous to amino acid residues present in an amyloid protein or amyloid peptide. Accordingly, Applicants' sequence search does not address whether the peptide of the Fu et al article anticipates the first, second, third, or fourth peptidyl sequences of claim 1. For all the reasons set forth above, Applicants have not rebutted the prima facie case of anticipation, i.e. Applicants have not demonstrated that the peptide of the Fu et al article does not satisfy the functional limitations set forth in claim 1. The rejection is maintained.

The rejection of claims 1, 2, 6-8, 20, 21, 51, and 52 over the Fu dissertation (Louisiana State University, December 2002) is maintained. The declaration by Hammer under 37 CFR 1.132 filed December 23, 2005 does not state exactly who is the inventor of each of the anticipatory peptides, and does not state exactly who is the inventor of each of the claims against which the peptides are applied. Accordingly, there is insufficient evidence to conclude that the reference's disclosure is not "by another" and is therefore unavailable as prior art under 35 U.S.C. 102(a). It appears that there are numerous prior art peptides, some of which were invented by Fu and Hammer (see the sentence bridging pages 3 and 4 of the Hammer declaration), at least one of which was invented by McLaughlin, Fu, Miller, and Hammer (see the sentence bridging pages 2 and 3 of the Hammer declaration), and others of which were invented by some other combination of the named inventors (see page 4, third full sentence, of the Hammer declaration). It also appears that different claims present in the application have different inventorships (see the inference of inventorship made by the examiner with respect to claim 54 in the discussion of the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001)). In order to show that the "by another" requirement of 35 U.S.C. 102(a) is not satisfied, Applicants will have to account for these differences in inventorship.

The rejection of claims 1, 2, 5, 7, 8, 20, 21, 51, and 52 over the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003, is maintained. The declaration by Hammer under 37 CFR 1.132 filed December 23, 2005 does not clearly state who is the inventor of the AMY-1 and AMY-3 peptides taught in the Aucoin oral presentation. In section 7, lines 16-19, it

appears that McLaughlin, Fu, Hammer, and Miller are inventors of the peptides. In section 7, lines 21-23, the declaration may be implying that Aucoin is also an inventor of the peptides. Inventor McCarley is not mentioned in this part of the declaration. However, there are six named inventors of the application, and accordingly it is not yet possible to conclude, from the statements made in the declaration, that the peptides taught in the Aucoin oral presentation are not "by another".

As noted by Applicants in their discussion of the Office action mailed July 22, 2005, claim 3 was incorrectly included in the rejections over the Fu dissertation (Louisiana State University, December 2002) and the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003. These references were not prior art against claim 3, and claim 3 should not have been listed as a rejected claim in these two rejections. The examiner apologizes for his error.

9. Claims 4, 9-18, and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

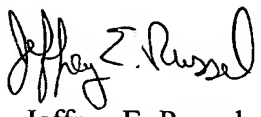
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

January 26, 2006